

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION**

RON MIKESELL, <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	
v.)	CAUSE NO. 3:16-CV-304-JD-MGG
)	
ST. JUDE MEDICAL, INC. <i>et al.</i> ,)	
)	
Defendants.)	
)	

REPORT AND RECOMMENDATION

On August 19, 2016, Defendants, St. Jude Medical, Inc. and Pacesetter, Inc. (collectively, “St Jude”), filed their Motion to Dismiss. On August 24, 2016, Plaintiffs, Ron and Beverly Mikesell, filed their response in opposition to St. Jude’s motion. St. Jude’s motion became ripe on September 6, 2016, when St. Jude filed a reply brief. On October 7, 2016, St. Jude’s motion was referred to the undersigned for a report and recommendation pursuant to [28 U.S.C. § 636\(b\)\(1\)\(B\)](#), Fed. R. Civ. P. 72(b), and N.D. Ind. L.R. 72-1(c). For the reasons stated below, the undersigned recommends that St. Jude’s motion be **GRANTED**. [[DE 10](#)].

I. RELEVANT BACKGROUND

On April 19, 2016, Plaintiffs filed their complaint raising four claims—strict liability—manufacturing defect (Count I), negligence in manufacturing (Count II), negligence *per se* (Count III), and loss of consortium (Count IV). Plaintiffs’ claims are based on allegations that Mr. Mikesell was injured as the result of manufacturing defects in the St. Jude Riata and Riata ST Leads (“Riata Leads” or “Leads”) implanted in him in 2005 as part of an implantable cardiac

defibrillator (“ICD”).¹ [DE 6 at 1, ¶ 1]. The Riata Leads, manufactured by St. Jude, are wires attached to ICDs “that deliver[] signals that allow an [ICD] to detect an abnormal heart rhythm and deliver a shock to help the heart return to an appropriate rhythm.” *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1203 (8th Cir. 2010).

According to Plaintiffs’ complaint, St. Jude introduced its Riata Leads, a Class III medical device, to the American market in about 2002 after securing approval for its design, manufacturing method, and labeling from the Food and Drug Administration (“FDA”). Class III medical devices “present a potential unreasonable risk of illness or injury and therefore incur the FDA’s strictest regulation.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 344 (2001) (quoting 21 U.S.C. § 360c(a)(1)(C)(ii)(II)) (internal quotations omitted). Before they may enter the market, Class III medical devices must undergo the rigorous premarket approval process (“PMA”), designed to provide the consuming public with “reasonable assurance that such device is safe [and effective] under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.” *Id.* (quoting 21 U.S.C. § 360e(d)(2)(A)–(B)).

Plaintiffs allege in their complaint that from January 2003 through 2010, after securing initial approval of the Leads through the PMA process, St. Jude submitted multiple PMA Supplements through which it sought and received approval to manufacture additional models of Leads as well as to make modifications to the original Riata Leads. [DE 6 at 5–7, ¶¶ 16–32]. Plaintiffs more specifically allege that “St. Jude applied for over 27 manufacturing or process changes to the Riata Leads” between 2005 and 2010 and that “St. Jude failed to manufacture the Riata Leads consistent with these approved changes, thereby creating a defective product.” [*Id.*

¹ In their complaint, Plaintiffs refer to Mr. Mikesell as “the decedent” multiple times. [DE 6 at 1, ¶ 1; 2, ¶ 6; 12, ¶ 60]. Because of other references in the Complaint [*Id.* at 2, ¶¶ 5, 7; 12, ¶ 64] combined with Plaintiffs’ failure to challenge St. Jude’s assumption that he is alive [DE 11 at 8 n.1], the undersigned also assumes that Mr. Mikesell is alive.

[at 7](#), ¶ 32]. In the section of their complaint entitled “Manufacturing Defects with Regard to Riata Leads,” Plaintiffs allege that the defects resulting from St. Jude’s alleged failure to comply with the 27 manufacturing or process changes violated the PMA and included “inconsistent insulation diameters surrounding the electric conductors,” [\[Id.](#), ¶ 33], inconsistent application of “a lubricious interface between the inner and outer insulation,” [\[Id. at 8](#), ¶ 36], “reduced tensile strength of the silicone insulation” as the result of “failure to comply with approved methods of curing and sterilization during the manufacture of the Leads,” [\[Id.](#), ¶ 37], and “insecure crimps over the length of the Lead” resulting from “failure to crimp with a controlled, uniform, degree of force” [\[Id.](#), ¶ 38].

Plaintiffs also allege that St. Jude sent two advisories, one in 2010 and one in 2011, to doctors regarding the Riata Leads. St. Jude acknowledges that on December 21, 2011, the FDA reclassified St. Jude’s advisories as a Class I Recall as Plaintiffs alleged. [\[Id. at 10](#), ¶ 46; [DE 11 at 9](#)]. According to Plaintiffs, “the FDA indicated that the reason for the recall was that ‘failures associated with lead insulation abrasion on the St. Jude [Riata Leads] may cause the conductors to become externalized,’ which “may cause serious adverse health causes [sic]², including death.” [\[DE 6 at 10](#), ¶ 48].

Plaintiffs assert that Mr. Mikesell “first learned that his Riata [L]ead had been recalled on or about August 2014” and that “[o]n October 03, 2014, [he] underwent invasive surgery to remove and replace the defective Riata Lead of his pacemaker.” [\[Id. at 2](#), ¶ 6]. Plaintiffs further allege that “[a]s a result of the defect in his Riata lead, [Mr. Mikesell] is now 100 percent dependent upon his pacemaker when he formerly was only 40 percent dependent upon his pacemaker.” [\[Id.](#), ¶ 7].

² The Court assumes that Plaintiffs meant to use the word “consequences” instead of “causes.”

Plaintiffs’ strict liability–manufacturing defect claim (Count I) alleges that “the defendant [sic]³” was injured “as a direct and proximate result of the manufacturing defect resulting “because the actual manufacture of the Riata Leads differs from the specifications set forth in the PMA and the conditions for approval.” [*Id.* at 12, ¶¶ 56–61]. Through their negligence in manufacturing claim (Count II), Plaintiffs allege that St. Jude breached its duty to manufacture the Riata Leads consistent with the PMA and conditions of approval and that St. Jude’s breach directly and proximately caused Mr. Mikesell’s injuries. [*Id.*, ¶¶ 62–64]. Plaintiffs’ negligence *per se* claim (Count III) is based on St. Jude’s alleged failure to comply with twenty specific Federal Regulations and the Conditions of Approval for the Leads, which allegedly were the direct and proximate cause of Mr. Mikesell’s injuries. [*Id.* at 13, ¶¶ 65–70]. And lastly in Count IV, Mrs. Mikesell alleges that she “suffered and will continue to suffer the loss of services and consortium of her husband” as a direct and proximate result of the St. Jude’s negligence. [*Id.*, ¶ 71].

In the instant motion to dismiss, St. Jude argues that Plaintiffs have failed to state any claim. Specifically, St. Jude contends that (1) Counts I and II fail to satisfy the Rule 8 pleading requirements and are also expressly pre-empted under 21 U.S.C. § 360k(a) [DE 11 at 17–27]; (2) Count III is inadequately pleaded and is also impliedly pre-empted because there is no private right of action to enforce the FDCA [*Id.* at 27–31]; and (3) Count IV must be dismissed with the other claims because it is dependent upon them and cannot stand alone [*Id.* at 31–32].

II. ANALYSIS

A. Manufacturing Defect Claims: Count I (Strict Liability) and Count II (Negligence in Manufacturing)

1. Express Preemption

³ The Court assumes that Plaintiffs meant to reference Mr. Mikesell specifically rather than “the defendant.”

Claims arising from Class III medical devices with premarket approval are limited under the 1976 Medical Device Amendments (“MDA”) to the Food, Drug, and Cosmetics Act (“FDCA”). Specifically, [21 U.S.C. § 360k\(a\)](#) prohibits states from

establish[ing] or continu[ing] in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

In *Riegel v. Medtronic, Inc.*, the United States Supreme Court established a two-step preemption analysis. [552 U.S. 312, 321–22 \(2008\)](#). In determining whether a state law claim is expressly preempted under [21 U.S.C. § 360k](#), court must first ascertain “whether the Federal Government has established requirements applicable to” the specific medical device. [Id. at 321](#).

Requirements imposed on the manufacture of medical devices through the FDA’s premarket approval (“PMA”) process constitute such federal requirements. [Id. at 322–23](#). With such federal requirements in place, the court must “then determine whether the [plaintiff’s] common-law claims are based upon [state] requirements with respect to the device that are ‘different from, or in addition to,’ the federal ones, and that relate to safety and effectiveness. [Id. at 321–22](#) (quoting [21 U.S.C. § 360k\(a\)](#)).

Here, device-specific federal requirements have been imposed on the Riata Leads at issue in this case through the PMA process. *See id.* at 322–23. Therefore, the first step in the preemption analysis is satisfied and the second step is the key to determining whether Plaintiffs’ manufacturing defect claims are expressly preempted. In *Riegel*, “the Court found that the state requirements implicit in the [plaintiffs’] common law [tort] claims were different from or in addition to the federal requirements and were preempted under section 360k.” [Bausch v. Stryker](#)

Corp., 630 F.3d 546, 552 (7th Cir. 2010). Yet the *Riegel* Court “limit[ed] its holding to claims that the device at issue ‘violated state tort law *notwithstanding compliance with the relevant federal requirements.*’” *Id.* (quoting *Riegel*, 552 U.S. at 330 (emphasis added)). Accordingly, lower courts should “allow claims to proceed when they are based on claimed violations of federal law.” *Id.* “[Section] 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations.” *Riegel*, 552 U.S. at 330. “The presence of a damages remedy does not amount to the additional of different ‘requirement’ that is necessary under [Section 360k]; rather, it merely provides another reason for manufacturers to comply with identical existing ‘requirements’ under federal law.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996). Thus, “section 360k protects a medical device manufacturer from liability to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law” or where “state law is parallel to federal law.” *Bausch*, 630 F.3d at 552.

State requirements are parallel to federal requirements when they are genuinely equivalent. *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005) (citing *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 454 (2005)). “To state a parallel claim and avoid preemption, [a plaintiff] must show that [state] law imposes a requirement or duty that is ‘genuinely equivalent’ to the federal reporting requirements that were allegedly violated.” *McAfee v. Medtronic, Inc.*, No. 1:12-CV-417 RLM, 2016 WL 2588807, at *3 (N.D. Ind. May 5, 2016) (citing *Bates*, 544 U.S. at 454; *Wolicki-Gables v. Arrow Int’l, Inc.*, 634 F.3d 1296, 1300–01 (11th Cir. 2011); *McMullen*, 421 F.3d at 489.) “State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law.” *McMullen*, 421 F.3d at 489.

In this case, Plaintiffs strict liability and negligence in manufacturing claims are potentially parallel because they depend upon alleged violations of the federal PMA requirements and the Conditions of Approval for the Riata Leads. *See* [DE 6 at 12](#), ¶¶ 57, 62–63. Specifically, Plaintiffs allege that the Riata Leads were manufactured in violation of PMA requirements for “[c]onsistent insulation diameters surrounding the electric conductors,” [*Id.* at [7](#), ¶ 33]; consistent application of “a lubricious interface between the inner and outer insulation,” [*Id.* at [8](#), ¶ 36]; compliance “with the approved methods of curing and sterilization,” [*Id.*, ¶ 37]; and “application of a controlled, uniform degree of force when applying the crimp” [*Id.*, ¶ 38].

St. Jude argues, however, that Counts I and II cannot be parallel because at least four of the federal requirements Plaintiffs allege do not actually exist. Specifically, St. Jude contends that the PMA and PMA Supplements do not include requirements for consistent insulation diameters, a lubricious interface, a particular method of curing, or application of a uniform degree of force. In support of this contention, St. Jude cites *Pinsonneault v. St. Jude Med., Inc.*, No. 12-CV-1717 PJS/JSM, 2014 WL 2879754, at *9–*11 (D. Minn. June 24, 2014). In *Pinsonneault*, the plaintiffs alleged—exactly as Plaintiffs in this case allege—that St. Jude manufactured defective Riata Leads by failing to comply with the PMA requirements for “uniform insulation thickness; . . . uniform degree of force when crimping the lead wires;” use of “approved methods and specifications for curing” and for sterilizing; and consistent application of a lubricious interface between the inner and outer insulation.” *Id.* at *4. The court ultimately granted summary judgment to St. Jude because the plaintiffs had failed to cite evidence of any such requirements. *Id.* at *9–*11. In addition, the Court found that St. Jude had presented “evidence that, standing alone, prove[d] by a preponderance of the evidence that there are no [such] federal requirements.” *Id.* at *8.

The *Pinsonneault* court appropriately considered the evidence before it at the summary judgment stage. Before this Court, however, is St. Jude’s motion to dismiss where evidence is not the focus of the analysis. Indeed, “much of the critical information” related to Class III medical devices such as Riata Leads, “is kept confidential as a matter of federal law.” *Bausch*, 630 F.3d at 560. For instance, “[t]he specifications of the FDA’s premarket approval documents . . . are confidential, and there is not public access to complete versions of these documents.” *Id.* As a result, injured patients like Mr. Mikesell “cannot gain access to that information without discovery.” *Id.* (citations omitted). Just because the *Pinsonneault* plaintiffs did not meet their burden to show that these requirements exist does not mean that Plaintiffs here should be precluded from the opportunity afforded through discovery to determine whether evidence exists to show that such requirements exist.

With that said, St. Jude may still be able to present evidence—maybe even the same evidence considered in *Pinsonneault*—that tips the scales in favor of their preemption position. Such a finding on the instant motion to dismiss, however, would be premature. Based on the complaint alone, Plaintiffs’ Counts I and II present potentially parallel claims that might not be expressly preempted and should not be dismissed as a result.

However, parallel claims that survive preemption must still “allege facts . . . establishing a causal nexus between the alleged injury and the [alleged federal] violation.” *Erickson v. Boston Sci. Corp.*, 846 F. Supp. 2d 1085, 1092 (C.D. Cal. 2011); accord *McAfee*, 2016 WL 2588807, at *1 (citing *Bates*, 544 U.S. at 454; *Wolicki-Gables v. Arrow Int’l, Inc.*, 634 F.3d 1296, 1300–01 (11th Cir. 2011); *McMullen*, 421 F.3d at 489.) Moreover, the plaintiff must meet the Rule 12(b)(6) pleading standard by alleging “facts sufficient to meet the new ‘plausibility’

standard applied in *Iqbal* and *Twombly*.” *Bausch*, 630 F.3d at 558. This is where Plaintiffs’ manufacturing defects claims in Counts I and II fail.

2. Pleading Parallel Claims

Under Fed. R. Civ. P. 12(b)(6), dismissal of a complaint is appropriate when the complaint fails to allege a cause of action for which relief can be granted. Federal law only requires a plaintiff to provide a short and plain statement of the claim that the pleader is entitled to relief. Fed. R. Civ. P. 8; see *Bartholet v. Resihauer A.G. (Zurich)*, 953 F.2d 1073, 1078 (7th Cir. 1992). When considering a 12(b)(6) motion to dismiss, the court should “construe the complaint in the light most favorable to the plaintiff, accepting as true all well-pleaded facts alleged, and drawing all possible inferences in her favor.” *Tamayo v. Blagojevich*, 526 F.3d 1074, 1081 (7th Cir. 2008). “However, [the court] need not ignore facts set forth in the complaint that undermine the plaintiff’s claim or give weight to unsupported conclusions of law.” *Buchanan-Moore v. Cty. of Milwaukee*, 570 F.3d 824, 827 (7th Cir. 2009); accord *Bogie v. Rosenberg*, 705 F.3d 603, 609 (7th Cir. 2013).

A complaint that states a plausible claim for relief survives a motion to dismiss. See *Ashcroft v. Iqbal*, 556 U.S. 662, 677–79 (2009); see also *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007) (holding that the pleading stage does not impose a probability requirement but does require alleged facts to be plausible so as to entitle a person to relief even if recovery is remote and unlikely). Put another way, a complaint survives a motion to dismiss if it “contains sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). “[T]he plausibility standard [asks] for more than a sheer possibility that a defendant has acted unlawfully.” *United Food &*

Commercial Workers Unions & Emp'rs Midwest Health Benefits Fund v. Walgreen Co., 719 F.3d 849, 853 (7th Cir. 2013) (internal quotations and citations omitted).

Consequently, “a court need not accept as true ‘legal conclusions[, or t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements.’” *Brooks v. Ross*, 578 F.3d 574, 581 (7th Cir. 2009) (quoting *Iqbal*, 556 U.S. at 678). Indeed, such conclusory statements are not entitled to the presumption of truth. *McCauley v. City of Chicago*, 671 F.3d 611, 616 (7th Cir. 2011). With conclusory statements properly discounted, the court can then “determine whether the remaining factual allegations plausibly suggest an entitlement to relief. *Id.* (internal quotations and citations omitted). A complaint fails if “it tenders ‘naked assertion[s]’ devoid of ‘further factual enhancement.’” *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557).

In *Bausch*, the Seventh Circuit found that plaintiffs had sufficiently pleaded their parallel manufacturing defect claims. The *Bausch* complaint alleged that the medical device at issue was “unreasonably dangerous, causing plaintiff to suffer an unstable right hip, pain, suffering, disability, and what is euphemistically called ‘revision’ surgery.” 630 F.3d at 558. Plaintiffs here comparably allege that the manufacturing defect—allegedly arising from St. Jude’s manufacture of the Riata Leads using specifications different from those set forth through the PMA and its accompanying Conditions for Approval—“renders the Riata Lead unreasonably dangerous for its intended use and Plaintiff could not have anticipated the danger the defect in this product created.” [DE 6 at 12, ¶¶ 57–58]. However, the *Bausch* complaint went on to allege more facts, for which no counterpart exists in Plaintiffs’ complaint.

For instance, the *Bausch* plaintiffs alleged that “defendants knew, or at least should have known, before plaintiff’s original surgery that the [device] implanted . . . was defective.”

Bausch, 630 F.3d at 559. The *Bausch* complaint also alleged that six days before the plaintiff's surgery implanting the device at issue, the FDA had issued a letter to the defendants warning that the device was "adulterated due to manufacturing methods . . . not in conformity with industry and regulatory standards." *Id.*

Plaintiffs here allege nothing as to St. Jude's knowledge of defects or any recall of the Riata Lead before it was implanted into Mr. Mikesell in 2005. In fact, Plaintiffs' allegations appear to be based on St. Jude's failure to comply with modifications to the Riata Leads approved between 2005 and 2010, presumably after Mr. Mikesell's Leads were implanted. Moreover, the 2010 and 2011 advisories had not been issued when Mr. Mikesell's Leads were implanted bringing into question even the possibility that the specific Leads implanted in Mr. Mikesell could have been affected by the violations of federal requirements Plaintiffs allege.

Furthermore, the *Bausch* complaint relied on additional specific factual allegations including that "[a] device bearing the same catalogue number as the device allegedly not in compliance with regulations, was then implanted in Bausch's body the next week . . . failed. . . and was later recalled." *Id.* Plaintiffs' complaint here, however, alleges nothing as to the identification of the specific device implanted in Mr. Mikesell. Moreover, the *Mikesell* complaint alleges that a manufacturing defect in the Riata Leads caused Mr. Mikesell's injuries without actually alleging that the specific device implanted in Mr. Mikesell failed or what symptoms he experienced as a result of the allegedly defective device implanted. The allegations in the complaint seem to do a good job of pleading that Riata Leads suffered from defects generally, but not that the specific Leads implanted in Mr. Mikesell were defective or that any defect in those Leads specifically actually increased Mr. Mikesell's dependence on his

pacemaker by 60 percent—his alleged injuries. Without such detail, Plaintiffs’ manufacturing defect claims fail to meet the *Iqbal/Twombly* plausibility standard.

The Court acknowledges that discovery may be necessary to plead with specificity details about the PMA requirements or other matters kept confidential by St. Jude. See [Bausch](#), 630 F.3d at 560. However, “a plaintiff’s pleading burden should be commensurate with the amount of information available to them.” *Id.* at 561 (quoting and adopting the dissenting position in *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1212 (8th Cir. 2010) (Melloy, J., dissenting)). While the plaintiff in *Bausch* pled sufficiently based on the information to which she had access, Mr. and Mrs. Mikesell have not done so here.

Mr. Mikesell experienced life with the implanted and allegedly defective Riata Lead. He also alleged that the alleged defect could result in “Oversensing (leading to inhibition of pacing or inappropriate high voltage therapy); . . . Undersensing; . . . Loss of capture; . . . Changes in pacing and/or high voltage lead impedences; and . . . Inability to deliver high voltage therapy.”⁴ [\[DE 6 at 9, ¶ 42\]](#). Such symptoms of device failure should have been known to him either experientially or through reports from his doctor before, during, or after the October 2014 replacement surgery. It seems obvious that a patient would recognize if the pacing of the device was inhibited or if the device was misapplying high voltage therapy. None of those specific failures of Mr. Mikesell’s device is alleged here.

Furthermore, facts that Plaintiffs have alleged bring into question whether the device actually failed at all. For instance, Plaintiffs allege that the Riata Leads were recalled in 2011, but that Mr. Mikesell first learned of the recall in August 2014. The complaint alleges nothing as to the sequence of events that led to the discovery of the recall. Moreover, had the device failed,

⁴ Notably, Plaintiffs’ complaint alleges nothing, even generally, about the potential for the alleged defects in the Riata Leads to cause increased dependence on a pacemaker, Mr. Mikesell’s only alleged injury.

Mr. Mikesell would likely have been discussing symptoms of the failure with his physician, which in turn would have probably led to an earlier discovery of the recall. In addition, the complaint alleges nothing besides the recall as the rationale for the replacement surgery in October 2014. The recall alone does not suggest that Mr. Mikesell's Riata Leads specifically failed, just that they could fail.

Taken together, Plaintiffs' pleadings in Counts I and II do not allege facts that even taken as true could establish a causal nexus between Mr. Mikesell's increased dependence on his pacemaker and St. Jude's alleged violations of the PMA requirements. *See Erickson*, 846 F. Supp. 2d at 1092. Therefore, the undersigned recommends granting St. Jude's motion to dismiss as to Plaintiffs' strict liability (Count I) and negligence in manufacturing (Count II) claims based on manufacturing defects.

B. Negligence Per Se Claim: Count III

1. Implied Preemption

Congress has declared that all actions to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). As a result, there is no private right of action to enforce the FDCA. *Buckman*, 531 U.S. at 349 n.4. As already alluded to above,

Riegel and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).

Medtronic Leads, 623 F.3d at 1204 (quoting *Riley v. Cordis Corp.*, 625 F.Supp.2d 769, 777 (D.Minn.2009); accord *Bausch*, 630 F.3d at 557–58. As a result, any state-law claim that simply seeks to enforce a manufacturer's duty to comply with federal regulations is subject to implied preemption.

For example, the United States Supreme Court held that a fraud on the FDA claim was impliedly preempted. *Buckman*, 531 U.S. at 353. The *Buckman* claim alleged that a regulatory consultant had made fraudulent representations to the FDA while obtaining approval for a medical device and that those misrepresentations were the “but for” cause of the plaintiff’s injuries from implantation of the device. *Id.* at 343. Despite St. Jude’s arguments to the contrary, Plaintiffs’ negligence *per se* claim here is distinguishable from the fraud claim in *Buckman*. See *Bausch*, 630 F.3d at 557. “[T]he federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration.” *Buckman*, 531 U.S. at 348. Here, Plaintiffs do not ask the Court to enforce the PMA requirements and federal regulations at issue. Instead, Plaintiffs simply seek compensation for damages resulting from alleged violations of the federal requirements and regulations—a proper role for state law tort law. See *Riegel*, 552 U.S. at 330 (holding that states are not prohibited from providing a damages remedy for claims premised on a violation of FDA regulations); see also *Lohr*, 518 U.S. at 495 (stating that a state-law damages remedy is not preempted but “merely provides another reason for manufacturers to comply with identical existing ‘requirements’ under federal law.”).

Therefore, Plaintiffs’ negligence *per se* claim is not impliedly preempted. However, that does not end the inquiry because the negligence *per se* claim suffers the same pleading deficiencies that caused the undersigned to recommend that Counts I and II be dismissed.

2. Sufficiency of Pleadings

Even though Plaintiffs’ negligence *per se* claim may survive the implied preemption analysis, it must still meet the plausibility standard discussed above and articulated in *Iqbal* and *Twombly*. Plaintiffs allege that “St. Jude failed to comply with the Conditions of Approval and Federal Regulations.” [DE 6 at 13, ¶ 69]. Plaintiffs clearly identify twenty different regulations

that St. Jude allegedly violated. [[Id.](#), ¶ 67]. Yet Plaintiffs’ allegations based on these regulations are bare conclusions, bereft of any factual support that St. Jude actually could or did violate these regulations. In fact, St. Jude argues that many of the identified regulations are definitional such that they cannot be violated.

In addition, Plaintiffs’ complaint fails to plead sufficiently any causal connection—this time between St. Jude’s violations of these specific federal regulations and the Conditions of Approval for the Riata Leads and Mr. Mikesell’s increased dependence on his pacemaker. Without more, Plaintiffs’ negligence *per se* claim merely alleges the possibility, not the plausibility, that St. Jude violated federal law or caused Mr. Mikesell’s damages. As a result, the undersigned must also recommend that St. Jude’s motion to dismiss the negligence *per se* claim (Count III).

C. Loss of Consortium (Count IV)

The complaint alleges a loss of consortium claim only as to Mrs. Mikesell. [[DE 6 at 14](#), ¶ 71] (“As a direct and proximate result of the negligence of the Defendants, the Plaintiff has suffered and will continue to suffer the loss of services and consortium of her husband.”). “[A] claim of loss of consortium is a derivative claim and absent actionable injury to one spouse, the other spouse cannot recover for loss of consortium.” [Miller v. Cent. Ind. Cmty. Found., Inc.](#), 11 N.E.3d 944, 963 (Ind. Ct. App. 2014) (internal quotations and citations omitted). Plaintiffs do not dispute this statement of the law. In light of the recommendations discussed above dismissing all of Plaintiffs’ negligence claims, Mrs. Mikesell retains no loss of consortium claim because her spouse, Mr. Mikesell, lacks any actionable injury. Therefore, the undersigned also recommends dismissing Mrs. Mikesell’s loss of consortium claim (Count IV).

III. CONCLUSION

For the reasons stated above, Plaintiffs have failed to plead sufficiently claims for strict liability—manufacturing defect, negligence in manufacturing, and negligence *per se* against St. Jude. With no valid tort claims remaining, the predicate for Plaintiffs’ loss of consortium claim no longer exists. Therefore, the undersigned **RECOMMENDS** that St. Jude’s motion to dismiss be **GRANTED** as to all four counts in Plaintiffs’ complaint. [[DE 10](#)]. Should the Court **GRANT** St. Jude’s instant motion to dismiss as recommended, the undersigned also **RECOMMENDS** that Plaintiffs be **GRANTED** the opportunity to amend their complaint. *See Bausch*, 630 F.3d at 561–63.

NOTICE IS HEREBY GIVEN that within fourteen (14) days after being served with a copy of this recommended disposition a party may serve and file specific, written objections to the proposed findings and/or recommendations. [Fed. R. Civ. P. 72\(b\)](#). FAILURE TO FILE OBJECTIONS WITHIN THE SPECIFIED TIME WAIVES THE RIGHT TO APPEAL THE DISTRICT COURT’S ORDER.

SO ORDERED.

Dated this 2nd day of February 2017.

s/Michael G. Gotsch, Sr.
Michael G. Gotsch, Sr.
United States Magistrate Judge